

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE Group Art Unit 1651

I, Leslie Lindsay Smith, hereby certify that this

correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

Patent Application of

Juan DePablo, et al.

Application No. 10/657,017

Confirmation No.: 9034

Filed: September 5, 2003

Examiner:

"PRESERVATION AND STORAGE MEDIUM FOR BIOLOGICAL MATERIALS"

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR §1.97(b)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The Examiner's attention is directed to the references which are listed on the attached Form PTO/SB/08A and/or PTO/SB/08B. A copy of each reference identified by an "*" is enclosed. No other copies are not being provided herewith because, pursuant to 37 C.F.R. §1.98(d), copies were previously submitted to, or cited by, the office in U.S. Serial No. 09/625,735, filed July 26, 2000, which issued as U.S. Patent No. 6,653,062 on November 25, 2003, which is being relied upon for an earlier filing date under 35 U.S.C. §120.

Citation of these references is respectfully requested.

No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

Respectfully submitted,

Reg. No. 48,887

File No. 096429-9144 Michael Best & Friedrich LLP One South Pinckney Street P. O. Box 1806 Madison, WI 53701-1806 (608) 257-3501

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Application Number	10/657017	
Filing Date	September 5, 2003	
First Named Inventor	Juan DePablo	
Group Art Unit	3737	
Examiner Name		
Attorney Docket Number	096429-9144	

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
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	Ahmad N, Kashi H, Helmy H, Hadingham J, Potts DJ, Lodge JP. Renal preservation with phosphate buffered sucrose: comparison with hyperosmolar citrate in a prospective trial. <i>Transplant Proc.</i> 1997 FebMar.;29(1-2):355-6.		
	Arakawa et al., Stabilization of Protein Structure By Sugars, Biochemistry 21, 6536-6544, 1982.		
	Bando et al., Effects of Newly Developed Solutions Containing Trehalose on Twenty-Hour Canine Lung Preservation, <i>The Journal of Thoracic and Cardiovascular Surgery</i> 108, 1:92-98, 1994.		
	Beattie et al., Trehalose: A Cryoprotectant that Enhances Recovery and Preserves Function of Human Pancreatic Islets After Long-Term Storage, <i>Diabetes</i> 46, 519-523, 1997.		
*	Carpenter et al., Interactions of Stabilizers with Proteins During Freezing and Drying, American Cancer Society 9, 135-147, 1994.		
	Carpenter et al., Long-Term Preservation of Dried Phosphofructokinase by Sugars and Sugar/Zinc Mixtures, Cryobiology 25, 372-376, 1998.		
	Carpenter et al., Modes of Stabilization of a Protein by Organic Solutes During Desiccation, Cryobiology 25, 459-470, 1998.		
	Carpenter et al., Stabilization of Phosphofructokinase During Air-Drying with Sugars and Sugar/Transition Metal Mixtures, Cryobiology 24, 455-465, 1987.		
	Carpenter et al., Stabilization of Phosphofructokinase with Sugars During Freeze-Drying: Characterization of Enhanced Protection in the Presence of Divalent Cations, <i>Biochimica et Biophysica Acta</i> , 109-115, 1987.		
	Carpenter et al., The Mechanism of Cryoprotection of Proteins by Solutes, Cryobiology 25, 244-255, 1998.		

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U.S. PATENT DOCUMENTS					
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Initials		Document	Document		

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Attorney Docket Number

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	FOREIGN PATENT DOCUMENTS					
Examiner Initials	Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
	EP	0 356 257	Cryopharm Corporation	Feb., 1990		
	EP	0 508 496	Cryopharm Corporation	Oct., 1992		
	EP	0 580 444	Roussel Morishita Co., Ltd., et al.	Jan., 1994		
	EP	0 682 944	Bayol et al.	Nov., 1995		
	PCT	WO 95/20399	Ciba-Geigy Ag, et al.	Aug., 1995		
	PCT	WO96/05809	Colaco et al.	Feb., 1996		
	PCT	WO96/40077	Roser et al.	Dec., 1996		
	PCT	WO98/41188	Roser et al.	Sep., 1998		
	PCT	WO99/47174	Roser et al.	Sep., 1999		

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	English Translation of Fukumoto et al.
	English Translation of Migulina.
	Eroglu et al., Intracellular Trehalose Improves the Survival of Cryopreserved Mammalian Cells, <i>Nature Biotechology</i> 18, 163-167, 2000.
	Ford et al., The Effect of Carbohydrate Additives in the Freeze-Drying of Alkaline Phosphate, J. Pharm Pharmacol 45, 86-93, 1992.
	Franks et al., Using Water-Soluable Glasses as a Strategy for Bioproduct Stabilization, <i>Pafra Biopreservation</i> , Cambridge, U.K., 1 pg.
	Freshney, Culture of Animal Cells, 3rd Ed., 85, Wiley-Liss, 1994.
	Freshney, Culture of Immortalized Cells 186, Wiley-Liss, 1996.
	Fukumoto et al., Effect of Various Additives on Long-Term Preservation of Cucumber Mosaic in vitro, Ann. Phytophath Soc. Japan 46, 448-54, 1980.
	Goldin, Barry R., "Health Benefits of Probiotics" British Journal of Nutrition 80 Suppl. 2, S203-S207, 1998.
	Guo et al., Trehalose Expression Confers Desiccation Tolerance on Human Cells, <i>Nature Biotechnology</i> 18, 168-171, 2000.

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	Hirata et al., Effects of Trehalose in Canine Lung Preservation, Surgery 115, 1:102-107, 1994.		
	Hopkinson et al., Comparison of Saccharides as Osmotic Impermeants During Hypothermic Lung Graft Preservation, <i>Transplantation</i> 61, 12:1667-1671, 1996.		
	Isowa et al., Trehalose-Containing Solutions Enhance Preservation of Culture Endothelial Cells, Ann. Thoracic Surgery, 61:542-545, 1996.		
	Izutzu et al., Cryprotection of LDH of Amphiphilic Excipients, Biotechnology and Bioengineering 43, No. 11, 1994.		
	Izutzu et al., Stabilizing Effect of Amphiphilic Excipients on Freeze-Thawing and Freeze-Drying of Lactate Dehydrogenase, Biotechnology and Bioengineering 43, 1102-1107, 1994.		
	Kaufman, et al., Ed., Handbook of Molecular and Cellular Methods in Biology and Medicine 350, CRC Press, 1995.		
	Kharche et al., Effect of Certain Dilutors on the Morphology of Ram Spermatoza on Preservation at 5C, <i>Indian Vet</i> . S 53, 694-98, 1976.		
	Kitahara, et al., Preservation of Skin Free-Flap Using Trehalose, Journal of Surgical Research 62, 1:130-134, 1996.		
	Lam FT, Mavor Al, Potts DJ, Giles GR. Improved 72-hour renal preservation with phosphate-buffered sucrose. Transplantation. 1989 May;47(5):767-71.		
	Leslie et al., Trehalose and Sucrose Protect Both Membranes and Proteins in Intact Bacteria During Drying, Applied Environmental Microbiology 61, 3562-3597, 1995.		

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	McCoy II, Cryobio Research May Lead to Increased Human Blood Supply, Mary Ann Liebert, Inc., New York, 1994.	
	Migulina, Preservation of Sheep's Blood for the Wasserman Reaction with Glucoboric-Saline Solution, Vestn. Derm. Vener 35, 3:40-47, 1961.	
	Miller et al., Monitor: Progress and Profiles, PSTT 1, No. 7, 1998.	
	Miller et al., Stabilization of Lactate Dehydrogenase Following Freeze-Thawing and Vacuum-Drying in the Presence of Trehalose and Borate, <i>Pharmaceutical Research</i> 15, 8:1215-1221, 1998.	
	Miller, et al., "Thermoph; ysical Properties of Trehalose and Its Concentrated Aqueous Solutions" <i>Pharmaceutical Research</i> 14, 5:578-590, 1997.	
	Onishi and Barr, "Simplified Method for Quantitating Protein using Biuret and Phenol Reagents" Analytical Biochem 86:193-200, 1978.	
	Perzon et al., Reversible Gel Formation Induced by Ion Complexation, Macromolecules 21, 1121-1125, 1998.	
	Pollard, et al., Ed., Basic Cell Culture Protocols 2 nd Ed., 471, Humana Press, 1997.	
	Roser et al., A Sweeter Way to Fresher Food, New Scientist, 1993, 4 pgs.	
	Saha et al., Normal Calves Obtained After Direct Transfer of Vitrified Bovine Embryos Using Ethylene Glycol, Trehalose and Polyvinylpyrrolidone, Cryobiology 33, 291-299, 1996.	

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First Named Inventor Juan DePablo

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	Sanders, Mary E., "Development of Consumer Probiotics for the US Market" British Journal of Nutrition 80, Suppl. 2, S213-S218, 1998.
	Sigma Product Information: Product No. P0261.
	Spieles, et al., <i>Cryo-Letters</i> 17, 43-52, 1996.
	Sutton, J., Chem. Soc. Faraday Trans 87, 3747, 1991.
	Vaughan et al., Probiotics in the New Millenium, Nahrung, (Food) 43, 3:148-153, 1999.
	Whitaker, Tissue and Cell Culture 14-15, Balliere Trindall, 1972.
	Yokomise et al., Long-Term Cryopreservation Can Prevent Rejection of Canine Tracheal Allografts with Preservation of Graft Viability, <i>The Journal of Thoracic and Cardiovascular Surgery</i> 111, 5:930-934, 1996.
	Zuidam et al., Gamma-Irradiation of Non-Frozen, Frozen, and Freeze-Dried Liposomes, <i>Pharmaceutical Research</i> 12(11):1761-68, 1995

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	U.S.	PATENT DOCUMENTS	
xaminer Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
	4411894	Schrank et al.	Oct., 1983
	4476221	Kane et al.	Oct., 1984
	4798824	Belzer et al.	Jan., 1989
	4806343	Carpenter et al.	Feb., 1989
	4806524	Kawaguchi et al.	Feb., 1989
	4857319	Crowe et al.	Aug., 1989
	4873230	Belzer et al.	Oct., 1989
	4891319	Roser	Jan., 1990
	5026566	Roser	Jun., 1991
	5149653	Roser	Sep., 1992
	5171661	Goodrich, Jr. et al.	Dec., 1992
	5252496	Kang et al.	Oct., 1993
	5314595	Fuller	May, 1994
	5512547	Johnson et al.	Apr., 1996
	5556771	Shen et al.	Sep., 1996
	5589167	Cleland et al.	Dec., 1996
<u> </u>	5621094	Roser et al.	Apr., 1997
	6468782	Tunnacliffe et al.	Oct., 2002
-	2001/00119819	Wolkers et al.	Sep., 2001
	2002/0009500	Wolkers et al.	Jan., 2003
	2002/0076445 *	Crowe, et al.	Jun., 2002
	5827741 *	Beattie, et al.	Oct., 1998
	2002/0114791 *	Crowe, et al.	Aug., 2002

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	Crowe et al., Is Trehalose Special for Preserving Dry Biomaterials?, <i>Biophysical Journal</i> , Chpt. 71, 2087-2093, 1996.
	Crowe et al., Preservation of Freeze-Dried Liposomes by Trehalose, Archives of Biochemistry and Biophysics 242, 240-267, 1985.
	Crowe et al., Preservation of Mammalian Cells-Learning Nature's Tricks, Nature Biotechnology 18, 145-167, 2000.
,	Crowe et al., Preserving Dry Biomaterials: The Water Replacement Hypothesis, Part 1, BioPharm 37, 28-33, 1993.
	Crowe, et al., <i>Cryobiology</i> , 20, 346-356, 1983.
	Crowe, et al., <i>Cryobiology</i> , 35, 20-30, 1997.
	Crystall, Glass Pharmacy: Preserved in Minute Beads of Sugar, Drugs Could Last for Years and Be Easier to Take, Too., New Scientist, 24-27, 1997.
	Darling, et al., Animal Cells-Culture and Media-Essential Data 22-23, John Wiley & Sons 1994.
	Dellman et al., Preservation of Fine Structure in Vibratome-Cut Sections of the Central Nervous System Stained for Light Microscopy, <i>Stain Technology</i> 58, 6:319-23, 1983.
	Dulbecco, et al., "Plaque Formation and Isolation of Pure Lines with Poliomyelitis Viruses" Journal of Experimental Medicine, 99:167-182, 1954.

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